PATENT
Attorney Docket No. 09404.0005-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Timothy John HENKEL	)	Group Art Unit: 1618
	)	
Application No.: 10/666,440	)	Examiner: M.P. YOUNG
	)	
Filed: September 19, 2003	)	
	)	Confirmation No.: 8311
For: METHODS OF TREATMENT	)	

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Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In accordance with Board Rule 41.37, Appellant presents this Appeal Brief as part of his request for reinstatement of the appeal. A Notice of Appeal accompanies the Brief. In view of the concurrently filed petition for a three month extension of time, the Notice of Appeal is due January 12, 2007. It and the Appeal Brief are therefore timely filed. This Appeal Brief responds to the July 12, 2007, rejection of claims 1 to 42, which have been twice rejected by the Office.

Pursuant to Rule 1204.01, Appellant requests that the previously paid appeal fees be applied to this appeal. Appellant paid the $500.00 fee required for filing a Notice of Appeal on June 1, 2006. The $500.00 fee for filing an Appeal Brief was paid on January 5, 2007. If Appellant's understanding regarding the fees is in error or if any additional or increase in fees are required, Appellant requests that the required fees be charged to Deposit Account No. 06-0916.

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Real Party In Interest

LG Life Sciences Limited is the real party in interest as shown by the assignment recorded at Reel 014979, Frame 0039, in parent application 09/953,736, filed September 17, 2001.

Related Appeals and Interferences

There are currently no other appeals or interferences, of which Appellant, Appellant's legal representative, or Assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status Of Claims

This application, as originally filed on September 19, 2003, included claims 1-14.

The Office mailed a first Office Action on the merits on June 4, 2004. Claims 1-14 were rejected.

Appellant filed an Amendment and Request for Reconsideration on November 30, 2004, in which he requested entry of new claims 15-42. Original claims 1-14 remained pending and under consideration.

On August 10, 2005, the Office issued a non-final rejection of claims 1-42.

Appellant responded to the Aug. 10, 2005, Office Action with a Request for Reconsideration on December 8, 2005. No claims were canceled, amended, or added.

The Office issued a final rejection of claims 1-42 on March 17, 2006.

On June 1, 2006, Appellant filed a Notice of Appeal and a Pre-Appeal Brief Request for Review. No claims were canceled, amended, or added.

The Office on July 7, 2006, issued a Notice of Panel Decision from Pre-Appeal Brief Review in which it indicated that the Appeal should proceed.

Appellant filed an Appeal Brief on January 5, 2007.

On March 6, 2007, the Office issued a Notification of Non-Compliant Appeal Brief.

On March 15, 2007, Appellant filed an Amended Appeal Brief.

The Office issued a non-final Office Action on July 12, 2007, in which it re-opened prosecution.

In summary, claims 1-42 stand rejected and are on appeal. A list of the claims on appeal appears in the Claim Appendix that begins on page i.

Status Of Amendments

Appellant has not filed any Amendments After Final. The Amendment filed November 30, 2004, was entered. Office Action mailed Aug. 10, 2005, page 2.

Summary Of Claimed Subject Matter

The claimed subject matter relates to the use of gemifloxacin for reducing the recurrences or severity of recurrences of acute exacerbations of chronic bronchitis (AECB). Substitute Specification, page 2, lines 22-29. Thus, in one embodiment, independent claim 1 recites a method of reducing the recurrences of AECB in a patient in need thereof comprising administering a therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof. Independent claim 1 is supported at least on page 2, lines 22-25, of the Substitute Specification.

In another aspect, independent claim 8 recites a method of reducing the severity of recurrences of AECB in a patient in need thereof comprising administering a therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof. Support for independent claim 8 is found at least on page 2, lines 26-29 of the Substitute Specification.

In some embodiments, the methods include conducting a long-term follow-up of the patient. *Id.*, page 10, lines 11-12. Independent claim 25 recites the method of claim 1, but includes this follow-up step. Accordingly, the specification provides support for independent claim 25 at least on page 2, lines 22-25 and page 10, lines 11-12.

Similarly, claim 34 recites the method of claim 8, but includes the follow-up step. Independent claim 34 finds support at least on page 2, lines 26-29 and on page 10, lines 11-12.

In any of the methods, the gemifloxacin can be gemifloxacin mesylate, including gemifloxacin mesylate sesquihydrate. *Id.*, page 3, lines 1-2. Dependent claims 2, 3, 9, 10, 27, 28, 32, 33, 36, 37, 41, and 42 recite those forms of gemifloxacin.

Dependent claims 4 and 11 recite that the treatment is acute, while dependent claims 5 and 12 recite that the treatment is elective. Both acute and elective treatments, and thus claims 4, 5, 11, and 12, are described on page 3, lines 11-23.

In certain embodiments, the gemifloxacin is administered orally once daily for 5 days, and the dosage can be 320 mg (calculated as the free base). Dependent claims 6, 13, 15-17, 21, 26, 31, 35, and 40 recite those aspects of the invention and are supported at least at page 4, lines 3-7 of the Substitute Specification.

As recited in dependent claims 7 and 14, one particular group of patients that is at risk for AECB are those patients with chronic obstructive pulmonary disease (COPD). *Id.*, page 3, lines 17-19.

Many patients have multiple AECBs each year. Thus, in one embodiment recited in dependent claims 18-20 and 22-24, the methods of the invention involve patients who have had from 1 to 4 AECBs in the past year. *Id.*, page 8, Table 1.

In those methods in which long-term follow-up is included as part of the method, that follow-up can be for a six month period following the start of gemifloxacin treatment, and may include clinical assessment during week 4-5, week 12, and week 26. This aspect of the invention is recited in dependent claims 29, 30, 38, and 39 and support for this aspect of the method is found at least on page 5, lines 1-2 and 12-15 of the Substitute Specification.

Grounds of Rejection

A. Claims 1, 4-8, 11-26, 34, and 35 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by File *et al.*, J. Chemotherapy, Vol. 12, pages 314-25 (August 2000) ("File").

B. Claims 2, 3, 9, 10, 27-33 and 36-42 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of File and WO 98/42705 to Kim *et al.* ("Kim").

Argument

I. Claims 1, 4-8, 11-26, 34, And 35 Are Patentable Over The File Reference Because It Is Not Available Under Any Section of 35 U.S.C. § 102

The Office first rejected claims 1, 4-8, 11-26, 34, and 35 as allegedly anticipated under 35 U.S.C. § 102(b) by the File reference in the Office Action mailed August 10, 2005. In that rejection, the Office asserted that File is available as a reference as of August 2000. Office Action mailed Aug. 10, 2005, page 2, ¶2.

As Appellants previously noted, this application claims benefit of provisional application no. 60/232,809, filed September 15, 2000, and provisional application no. 60/245,744, filed November 3, 2000. Consequently, File is not available as a reference under 35 U.S.C. § 102(b) since, even if it were available as of August 2000, that date is not more than one year before Appellant's earliest effective U.S. filing date. The Office has never asserted that Appellant is not entitled to benefit of the provisional application filing dates.

Further, in the Request for Reconsideration filed December 8, 2005, Appellant provided evidence in the form of a date stamp that the library at the National Institutes of Health did not receive the Journal of Chemotherapy, volume 12, no. 4 until November 3, 2000. A copy of the evidence relied upon by Appellant and previously considered by the Office is attached to this Brief.

The Office then took the position that the NIH date stamp was insufficient because "[u]nless conclusive evidence can be provided that the publisher of the article actively withheld the volume 12 issue of the Journal of Chemotherapy, there is no evidence to support that the article was not available until November of 2000." Office

Action mailed March 17, 2006, page 5. In addition, the Office also speculated that the reference may have been available on-line or with another library before November 2000, even though it provided no evidence in support of its position. *Id.* at 4-5.

In the July 7, 2006, Notice of Panel Decision from Pre-Appeal Brief Review, the Office stated that the "August 2000 publication date and print edition availability prior to Sept. 1, 2000 has been confirmed by communication with the publisher by our STIC library for the Fine reference." On August 2, 2006, the Office finally sent Appellant a copy of the e-mail exchange between the Office and the publisher of the Journal of Chemotherapy. A copy of that e-mail is attached as an Exhibit to this Brief.

Appellant argued in the Brief filed March 15, 2006, that the e-mail on which the Office relied did not provide evidentiary support for the Office's assertion. Specifically, Appellant pointed out that the e-mail stated only that the File article "is in our archives on our website and the print edition was mailed to subscribers around September 1, 2000." July 6, 2006, e-mail from Mary Forrest to Kristine Hensle. That statement, however, does not provide any evidence that the File reference was received by a member of the public before Appellant's effective filing date.

It is the Office, not Appellant, that bears the burden of determining the issue or publication date of a reference so that a proper comparison between the application and reference dates can be made. M.P.E.P. 706.02(a)(I). A journal article is not available as prior art until it is received by a member of the public. M.P.E.P. § 2128.02 (emphasis added) (citing *In re Schlittler*, 234 F.2d 882, 110 U.S.P.Q. 304 (CCPA 1956)). Further, while Internet disclosures and on-line databases can be relied upon by the Office, their date for the purposes of determining their availability as prior art is the date the item

was publicly posted. M.P.E.P. 2128. If, however, the publication does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. 102(a) or (b). *Id.*

Here, the e-mail from the publisher does not establish a publication date, nor does it provide any evidence that the File reference was retrieved from the publisher's archive before Appellant's effective filing date. Appellant has provided evidence in the form of a date stamp that File was not received by a member of the public until November 3, 2000. That date stamp is the only evidence in the record that addresses the date on which the File reference was received by a member of the public.

Nevertheless, in the July 12, 2007, Office Action that re-opened prosecution, the Office responded to Appellant's arguments by stating that "[i]t remains the position of the Examiner that the File reference would have been available to a member of the public before the filing of the priority documents of the instant invention." Office Action mailed July 12, 2007, page 4, ¶10. In support of its position, the Office points to the e-mail of the publisher of the File reference and characterizes it as showing that "[a]ccording to the publishers of the File article the reference was emailed to subscribers on or around September 1, 2000, approximately two weeks before the filing date of the provisional application." *Id.*, page 4-5, ¶10 (emphasis added). The Office goes on to state that "an email from the publisher of the article to subscribers (those of ordinary skill in the art with interest in the subject matter[)] would constitute dissemination of the article making the File reference available as prior art." *Id.* (emphasis added.)

Respectfully, this is a mischaracterization of the e-mail from the Journal of Chemotherapy to the USPTO's Biotechnology/Chemical Library. Ms. Forrest, the

Managing Editor of the Journal of Chemotherapy, did not state that the reference was e-mailed to subscribers around September 1, 2000, as the Office alleges. Instead, she stated that "the print edition was mailed to subscribers around September 1, 2000." July 6, 2006, e-mail from Mary Forrest to Kristine Hensle (emphasis added). A mail date is very different from an e-mail date. As discussed *supra*, a journal article that is mailed is not available as prior art until it is received by a member of the public. M.P.E.P. § 2128.02.

The Office has not met its burden of showing that the File reference was available to a member of the public before Appellant's effective filing data. In contrast, Appellant has provided evidence that File was not publicly available until November 3, 2000. The File reference is not prior art under section 102(b). Nor is it prior art under 35 U.S.C. § 102(a), which requires that the reference describe the invention in a printed publication "*before* the invention thereof by the applicant for patent in the United States." 35 U.S.C. § 102(a) (emphasis added). The File article is therefore not available as a reference under any section of 35 U.S.C. § 102. Accordingly, Appellant respectfully requests that the Board reverse the rejection.

II. Claims 2, 3, 9, 10, 27-33 And 36-42 Are Patentable Over The Combination of File And Kim Because File Is Not Available As A Reference Under Any Section of 35 U.S.C. § 102

The rejection under 35 U.S.C. § 103(a) relies upon the teachings of File. For the reasons discussed in Section I, File is not available as a reference under any section of 35 U.S.C. § 102. Accordingly, it cannot be relied upon as a reference in a rejection under 35 U.S.C. § 103(a) and Appellant respectfully requests that this rejection also be reversed.

Conclusion

For the reasons given above, pending claims 1-42 are allowable and reversal of the Examiner's rejections is respectfully requested.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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Steven P. O'Connor

Dated: December 14, 2007

By: Reg. No. 41,225 For
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Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)

1. A method of reducing the recurrences of acute exacerbations of chronic bronchitis (AECB) in a patient in need thereof comprising administering a therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof.

2. The method according to claim 1 comprising administering a therapeutically effective amount of gemifloxacin mesylate.

3. The method according to claim 2 comprising administering a therapeutically effective amount of gemifloxacin mesylate sesquihydrate.

4. The method according to claim 1 wherein gemifloxacin, or a pharmaceutically acceptable salt thereof, is administered as an acute treatment.

5. The method according to claim 1 wherein gemifloxacin, or a pharmaceutically acceptable salt thereof, is administered as an elective treatment.

6. The method according to claim 1 wherein gemifloxacin is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

7. The method according to claim 1 wherein the patient is suffering from chronic obstructive pulmonary disease.

8. A method of reducing the severity of recurrences of acute exacerbations of chronic bronchitis (AECB) in a patient in need thereof comprising administering a therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof.

9. The method according to claim 8 comprising administering a therapeutically effective amount of gemifloxacin mesylate.

10. The method according to claim 9 comprising administering a therapeutically effective amount of gemifloxacin mesylate sesquihydrate.

11. The method according to claim 8 wherein gemifloxacin, or a pharmaceutically acceptable salt thereof, is administered as an acute treatment.

12. The method according to claim 8 wherein gemifloxacin, or a pharmaceutically acceptable salt thereof, is administered as an elective treatment.

13. The method according to claim 8 wherein gemifloxacin is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

14. The method according to claim 8 wherein the patient is suffering from chronic obstructive pulmonary disease.

15. The method according to claim 4, wherein gemifloxacin is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

16. The method according to claim 11, wherein gemifloxacin is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

17. The method according to claim 1, wherein the therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof, is administered orally daily for five days.

18. The method according to claim 1, wherein the patient had from 1 to 4 AECBs in the last year.

19. The method according to claim 4, wherein the patient had from 1 to 4 AECBs in the last year.

20. The method according to claim 6, wherein the patient had from 1 to 4 AECBs in the last year.

21. The method according to claim 8, wherein the therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof, is administered orally daily for five days.

22. The method according to claim 8, wherein the patient had from 1 to 4 AECBs in the last year.

23. The method according to claim 11, wherein the patient had from 1 to 4 AECBs in the last year.

24. The method according to claim 13, wherein the patient had from 1 to 4 AECBs in the last year.

25. A method of reducing the recurrences of acute exacerbations of chronic bronchitis (AECB) in a patient in need thereof, comprising:

administering a therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof, to the patient, and

conducting a long-term follow-up of the patient;

thereby reducing the recurrences of AECB in the patient.

26. The method according to claim 25, wherein gemifloxacin or a pharmaceutically acceptable salt thereof is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

27. The method according to claim 26 comprising administering a therapeutically effective amount of gemifloxacin mesylate.

28. The method according to claim 27 comprising administering a therapeutically effective amount of gemifloxacin mesylate sesquihydrate.

29. The method according to claim 25, wherein the long-term follow-up is for a six month period following the start of gemifloxacin therapy.

30. The method according to claim 25, wherein the long-term follow-up comprises performing a clinical assessment of the patient during week 4-5, week 12, and week 26 following the start of gemifloxacin therapy.

31. The method according to claim 30, wherein gemifloxacin or a pharmaceutically acceptable salt thereof is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

32. The method according to claim 31 comprising administering a therapeutically effective amount of gemifloxacin mesylate.

33. The method according to claim 32 comprising administering a therapeutically effective amount of gemifloxacin mesylate sesquihydrate.

34. A method of reducing the severity of recurrences of acute exacerbations of chronic bronchitis (AECB) in a patient in need thereof, comprising:

administering a therapeutically effective amount of gemifloxacin, or a pharmaceutically acceptable salt thereof, to the patient, and

conducting a long-term follow-up of the patient;

thereby reducing the recurrences of AECB in the patient.

35. The method according to claim 34, wherein gemifloxacin or a pharmaceutically acceptable salt thereof is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

36. The method according to claim 35 comprising administering a therapeutically effective amount of gemifloxacin mesylate.

37. The method according to claim 36 comprising administering a therapeutically effective amount of gemifloxacin mesylate sesquihydrate.

38. The method according to claim 34, wherein the long-term follow-up is for a six month period following the start of gemifloxacin therapy.

39. The method according to claim 34, wherein the long-term follow-up comprises performing a clinical assessment of the patient during week 4-5, week 12, and week 26 following the start of gemifloxacin therapy.

40. The method according to claim 39, wherein gemifloxacin or a pharmaceutically acceptable salt thereof is administered orally at a dose of 320 mg (calculated as the free base) once daily for 5 days.

41. The method according to claim 40 comprising administering a therapeutically effective amount of gemifloxacin mesylate.

42. The method according to claim 41 comprising administering a therapeutically effective amount of gemifloxacin mesylate sesquihydrate.

Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)

As part of the Response filed December 8, 2005, Appellants submitted the cover page of Vol. 12, No. 4 of the Journal of Chemotherapy, along with a copy of the first page of the first article in that journal (Papandreou et al.) and a copy of the article by File published at pages 314-325. The first page of the Papandreou article bears a date stamp showing that the National Institutes of Health received Vol. 12 of the Journal of Chemotherapy on November 3, 2000.

On August 2, 2006, the Office forwarded to Appellant a copy of the e-mail exchange between the U.S. Patent and Trademark Office and the publisher of the File article. That e-mail exchange include the July 6, 2006, e-mail from Mary Forrest to Kristine Hensle discussed in this Brief.

Copies of this evidence is attached to this Appeal Brief.

Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)

There are no decisions in proceedings related to this appeal.